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Express Mail No. EB 132595207 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jerussi *et al.*	Confirmation No.:	4423
Serial No.:	10/720,134	Art Unit:	1621
Filed:	November 25, 2003	Examiner:	Paul A. Zucker
For:	DERIVATIVES OF VENLAFAXINE AND METHODS OF PREPARING AND USING THE SAME	Attorney Docket No: (CAM:	4821-531-999 208423-999528)

REQUEST FOR CORRECTED RECEIPT DATE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On November 5, 2007 a Response to Non-Final Office Action and Petition for Extension of Time (hereinafter "the Response") were mailed via express mail to the Commissioner for Patents in connection with the above-referenced U.S. patent application. However, the PTO receipt date for the Response is stamped November 6, 2007 (a copy of which is enclosed). In accordance with 37 CFR § 1.10(b), the Response was deposited directly with the United States Postal Service and accorded a clearly marked "date-in" of November 5, 2007. The date-stamped express mail receipt for express mail No. EB 132603053 US, which corresponds to the express mail number listed on the Response, is also enclosed.

As such, pursuant to 37 CFR § 1.10(c) and § 1.6(a)(2), Applicants hereby petition the Director to accord the Response a filing date of November 5, 2007, which is both the date of the Response and the "date-in" on the express mail receipt.

In Addition, Applicants paid for a one month extension of time for response. No additional fees are believed to have been charged in this matter, however if any extension

of time fee in excess of one month were inadvertently charged to Deposit Account No. 50-3013 in connection with the November 5, 2007 Response, the Commissioner is hereby authorized to credit such overpayment to Deposit Account No. 50-3013.

Respectfully submitted,

Date: February 1, 2008

Hoon Choi Ltd. Reg. No.: L0209
for: Anthony M. Insogna Reg. No.: 35,203
JONES DAY
222 East 41st Street
New York, New York 10017-6702
(212) 326-3939

Express Mail No. EB 132603053 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jerussi *et al.*	Confirmation No.:	4423
Serial No.:	10/720,134	Art Unit:	1621
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For:	DERIVATIVES OF VENLAFAXINE AND METHODS OF PREPARING AND USING THE SAME	Attorney Docket No: CAM:	4821-531-999 208423-999528

PETITION FOR EXTENSION OF TIME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is respectfully requested that the time for filing a response to the Office Action mailed July 5, 2007 be extended for a period of one month from October 5, 2007 to and including November 5, 2007.

The fee for this extension is estimated to be $120.00. Please charge the required fee to Jones Day Deposit Account No. 503013. A copy of this sheet is enclosed.

Respectfully submitted,

Date: November 5, 2007

Hoon Choi Ltd. Recog. No.: L0209
for: Anthony M. Insogna Reg. No.: 35,203
JONES DAY
12265 El Camino Real, Suite 200
San Diego, CA 92130
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Enclosure

11/08/2007 RFEKADU1 00000010 503013 10720134
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Express Mail No. EB 132603053 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jerussi *et al.*	Confirmation No.:	4423
Serial No.:	10/720,134	Art Unit:	1621
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For:	DERIVATIVES OF VENLAFAXINE AND METHODS OF PREPARING AND USING THE SAME	Attorney Docket No: CAM:	4821-531-999 208423-999528

RESPONSE PURSUANT TO 37 C.F.R. § 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Non-Final Office Action mailed July 5, 2007, Applicants submit the following remarks for the consideration by the Examiner and entry into the record of the above-captioned application. Also submitted herewith is a Petition for Extension of Time, with provision for the required fee.

Amendments to the Claims are reflected in the listing of the claims that begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-59. (Canceled).

60. (Previously Presented) A compound which is O-desmethylvenlafaxine succinate.

61. (Previously Presented) The compound of claim 60, wherein the compound is a hydrate of O-desmethylvenlafaxine succinate.

62. (Previously Presented) The compound of claim 61 which is O-desmethylvenlafaxine succinate monohydrate.

63. (Previously Presented) A pharmaceutical composition comprising a therapeutically effective amount of O-desmethylvenlafaxine succinate and a pharmaceutically acceptable carrier or excipient.

64. (Previously Presented) A pharmaceutical dosage form comprising a therapeutically effective amount of O-desmethylvenlafaxine succinate and a pharmaceutically acceptable carrier or excipient.

65. (Previously Presented) An oral dosage form comprising a therapeutically effective amount of O-desmethylvenlafaxine succinate and a pharmaceutically acceptable carrier or excipient.

66. (Previously Presented) The oral dosage form of claim 65, wherein the dosage form is a tablet or capsule.

67. (Previously Presented) The oral dosage form of claim 65, wherein the dosage form is a sustained release formulation.

68. (Previously Presented) The oral dosage form of claim 65, further comprising a rate controlling polymer material.

69. (CurrentlyAmended) The oral dosage form of claim 68, wherein the rate controlling polymer is ~~hydropropylmethyl~~ hydroxypropylmethyl cellulose.

70. (Previously Presented) The oral dosage form of claim 65, wherein the oral dosage form further comprises a binder.

71. (Previously Presented) The oral dosage form of claim 70, wherein the binder is microcrystalline cellulose.

72-78. (Canceled).

REMARKS

Claims 60-71 are pending in this application. Pursuant to a restriction requirement, claims 72-78 are canceled without prejudice to Applicants' right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications. Claim 69 is amended to correct a typographical error. No new matter has been introduced.

At the outset, Applicants respectfully invite the Examiner's attention to the fact that claims 60-71 define the same patentable invention as claimed in U.S. Patent No. 6,673,838 B2, which issued to Hadfield *et al.* on January 6, 2004. Applicants note that the claims of Patent No. 6,673,838 B2 were allowed over U.S. Patent No. 4,535,186, which forms the basis for the two obviousness rejections of the outstanding Office Action.

I. The Rejection Under 35 U.S.C. §103 Should be Withdrawn

In the Office Action, claims 60-66 and 70 are rejected as allegedly obvious over Patent No. 4,535,186 to Husbands *et al.* ("Husbands"). (Office Action, page 2). Further, claims 67-69 and 71 are rejected as allegedly obvious over Husbands in view of U.S. Patent No. 6,274,171 to Sherman *et al.* ("Sherman"). (*Id.*, page 4). Applicants respectfully traverse each of these rejections.

Even assuming, *arguendo*, that a *prima facie* case of obviousness were established, Applicants respectfully submit that any presumption of obviousness is rebutted for at least the following reasons.

Applicants respectfully invite the Examiner's attention to U.S. Patent No. 6,673,838 B2 to Hadfield *et al.* ("Hadfield"), which discloses unexpectedly improved properties of the succinic salt. In particular, Hadfield discloses that "[t]he results of the site-specific intestinal absorption of ODV [O-desmethylvenlafaxine] succinate and ODV fumarate show that ODV succinate has better absorption in the small intestine and in the colon than ODV fumarate." (Hadfield, Example 13, columns 24-26 and Figure 13). Specifically, Hadfield discloses that the rat intestinal permeability coefficients ("P_{Eff}") of the succinic salt are 0.912, 1.73, and 0.062[1] for the jejunum, ileum, and colon, respectively. (*Id.*). In contrast, the reported P_{Eff} values of the fumarate salt for the jejunum, ileum, and colon are 0.245, 0.678, and 0, respectively. (*Id.*). Based on the disclosed experimental P_{Eff} values, Hadfield discloses that

[1] 10^{-5} cm/sec.

while "the human *in vivo* Fa[2] of ODV succinate was predicted to be in the range of 60-77% in the small intestine and a Fa of 20% in the colon," the "*in vivo* Fa of ODV fumarate was estimated to be in the range of 33-45% in the small intestine and 0 in the colon, indicating [an] overall low absorption of this compound in the entire GI tract." (*Id.*) (emphasis added).

Consequently, Hadfield clearly discloses that the succinic salt of O-desmethylvenlafaxine is unexpectedly more advantageous than its fumarate salt. In view of these results, Applicants respectfully submit that any presumption of obviousness is rebutted, and thus, request that the rejection of claims 60-66 and 70 be withdrawn.

Second, with regard to claims 67-69 and 71, the Examiner alleges that these claims are "unpatentable over Husbands as applied to claims 60-66 and 70...and further in view of Sherman." (Office Action, page 4). Specifically, the Examiner alleges that Sherman "teaches extended release formulations of venlafaxine hydrochloride[,]...extended release formulations of venlafaxine and microcrystalline cellulose" and "coatings of hydroxypropylmethyl cellulose." (*Id.*). Regardless of the truth of this assertion, Applicants respectfully submit that claims 67-69 and 71, all of which depend ultimately from claim 65, are not obvious for at least the same reasons discussed above for claims 60-66.

II. Claim Objections

On page 5 of the Office Action, claim 69 is objected to because "[t]he word hydroxypropylmethylcellulose is misspelled." In this regard, claim 69 is amended to provide the correct spelling. Thus, Applicants respectfully request that the objection to claim 69 be withdrawn.

III. Conclusion

For at least the foregoing reasons, Applicants respectfully submit that all of the pending claims are allowable, and thus, request that their rejections be withdrawn.

[2] Fa = human fraction of dose absorbed.

No fee is believed due for the submission of this paper. However, if any fees are due for the submission of this paper or to avoid abandonment of this application, please charge them to Deposit Account No. 50-3013.

Respectfully submitted,

Date: November 5, 2007

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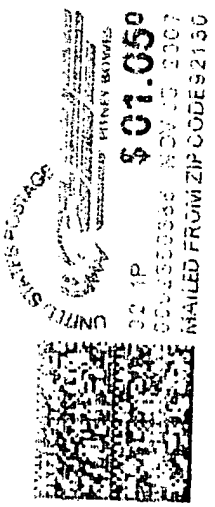

Express Mail No.: EB 132603053 US **Date Mailed:** November 5, 2007

Application No.: 10/720.134 **Filed:** November 25, 2003

Application of: Jerussi *et al.*

For: DERIVATIVES OF VENLAFAXINE AND METHODS OF PREPARING AND USING THE SAME

1. Response Pursuant to 37 C.F.R. § 1.111 (6 pages) with copy of cited United States Patent No. 6,673,838 B2 (32 pages); and
2. Petition for Extension of Time (one month) (1 page, in duplicate).

DOCKET: 4821-531-999
CAM: 208423-999528

Sender: Hoon Choi/Ltd Recog. No. L0209
For: Anthony M. Insogna/Reg. No. 35,203